

Reconsideration of the captioned application as amended herewith is respectfully requested.

The Office Action rejected claims 1 – 26 and 31 – 32 under 35 USC §103(a), as being unpatentable over Martindale; and rejected claims 1 – 26, 31, and 32 under 35 USC §103(a) as being unpatentable over the Diener, et al. publication (“Diener”) in view of United States Patent No.: 5,538,959 to Mauskop (“Mauskop”).

New claims 33 – 36 are added. Support for these new claims may be found in the Specification as originally filed in the parent application, U.S. Serial Number 09/449,124 filed on 24 November 1999 (hereafter “Parent Application”), at, for example, page 2, lines 1 – 16, and page 3, lines 1 – 3. In particular, Applicant wishes to clarify that the language “ibuprofen as the sole anti-migraine agent,” as used in the Parent Application, reflects that the “present invention relies on the action of a single active ingredient, i.e. ibuprofen.” As discussed later herein, this language is meant to exclude other components, such as magnesium, which possess anti-migraine properties, but it is not meant to exclude ibuprofen salts, ibuprofen isomers and the like (collectively “Salts”) wherein the non-ibuprofen component of such Salts, *per se*, does not possess such anti-migraine properties. In view of the above, Applicants respectfully submit that these claims do not introduce new matter into the Application under 37 CFR 1.121(f).

Claims 1 – 26 and 31 – 36 are pending in this application after entry of this Amendment.

**The Rejection of Claims 1 – 26 and 31 – 32 Under  
35 USC §103(a) Based on Martindale Has Been Overcome.**

Claims 1 – 26 and 31 – 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Martindale. Applicants respectfully disagree in view of the ensuing discussion.

According to the Office Action, Martindale teaches “that the vast majority of migraine attacks can be treated solely with mild analgesics such as acetaminophen.” Applicants respectfully disagree.

Martindale provides that “[m]igraine is characterized by recurrent attacks of headache which typically last 4 to 72 hours.... The headache is a unilateral pulsating pain that is aggravated by movement and is usually of sufficient severity to disturb or prevent daily activities. See Martindale, page 443, column 2. Martindale recommends that “[s]imple analgesics such as aspirin, NSAIDs or paracetamol are effective if taken at earliest signs of an attack,” i.e., the attack of a headache. However, Martindale fails to disclose or suggest: a) the use of ibuprofen, as opposed to a multitude of other NSAIDS, specifically for treating migraine; 2) the use of ibuprofen, alone, “as the sole anti-migraine agent;” or 3) that analgesics, let alone specifically NSAIDs or more specifically ibuprofen alone, is effective for treating or mitigating the particular symptoms claimed, i.e. photophobia or phonophobia.

Therefore, because Martindale fails to disclose or suggest several elements of Applicant’s claims, i.e., e.g., “mitigating or treating photophobia [/

phonophobia] associated with a migraine” with “ibuprofen as the sole anti-migraine agent” (emphasis added), Applicants respectfully submit that the rejection of claims 1 – 26 and 31 – 32 under 35 USC §103(a) has been overcome and should be withdrawn.

**The Rejection of Claims 1 – 26 and 31 – 32 Under 35 USC §103(a) Based on Diener in view of Mauskop Has Been Overcome.**

Claims 1 – 26 and 31 – 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Diener in view of Mauskop. Applicants respectfully disagree in view of the ensuing discussion.

Diener discloses that migraines are a disorder that includes various symptoms such as “headache, nausea, vomiting, photo-and phonophobia and malaise.” Diener, page 811, abstract. Diener further discloses that “[a]spirin, ibuprofen, and paracetamol (acetaminophen)” are useful analgesics for treating mild to moderate migraine attacks. Diener, page 813, column 2, lines 3 – 5. However, Diener fails to disclose or suggest that specifically ibuprofen is useful for the specifically claimed symptom, i.e., “mitigating or treating photophobia [/phonophobia] associated with a migraine” as claimed herein.

In addition, not only does Diener fail to disclose or suggest that migraines may be treated solely with an analgesic, but Diener further teaches away from the use of an analgesic, such as “ibuprofen[,] as the sole anti-migraine agent” by providing that an antiemetic should be administered first or in conjunction with an analgesic (emphasis added). See Diener, page 811 (emphasis added) and page 814, lines 1 - 3.

Mauskop teaches the use of a composition consisting essentially of: 1) an analgesic agent; 2) a magnesium salt; and 3) a stimulant for the alleviation of migraine symptoms such as photophobia and phonophobia. See Mauskop, Abstract. Ibuprofen is included as one of many possible analgesic compounds. See Mauskop, column 2, line 62 – claim 3, line 18. However, Mauskop expressly provides that “the combination of a magnesium salt and the analgesic agent(s) exert(s) a synergistic effect for relieving pain and related migraine symptoms.” Mauskop, column 3, lines 23 – 26.

Mauskop neither discloses or suggests the use of “ibuprofen, isomers thereof, or mixtures thereof” as the “sole anti-migraine agents” for the treatment or mitigation of photophobia or phonophobia as claimed herein. Further, Mauskop neither discloses or suggests the use of “ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole anti-migraine agents, [for the treatment or mitigation of photophobia or phonophobia] wherein the pharmaceutically acceptable salt of ibuprofen is :

- a) an inorganic cation salt selected from sodium, potassium, lithium, calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic;
- b) an organic salt of ibuprofen with primary, secondary, tertiary and quaternary amines selected from triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)aminomethane, methylglycamine, theobromine, puines, piperazine, piperidine, and polyamine resins; or
- c) mixtures thereof,”



as claimed herein.

In view of the fact that the cited references, either alone or in combination, fail to disclose or suggest the treatment or mitigation of photophobia and phonophobia via use of the claimed ibuprofen, ibuprofen isomer, and/or pharmaceutically acceptable salts of ibuprofen, as the "sole anti-migraine agents," Applicants respectfully submit that the rejection of claims 1 – 26 and 31 - 32 under 35 USC §103 as being unpatentable over Diener in view of Mauskop has been overcome and should be withdrawn.

### **Conclusion**

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

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Dated:  October 2003

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